# *KURZPROTOKOLL*
# *OlympiA*

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| **Öffentlicher Titel** | Phase III Studie zu Olaparib als adjuvante Therapie bei BRCA-Mutation und Her2-negativem primären Brustkrebs mit hohem Risiko |
| **Wissenschaftl. Titel** | A Randomised, Double-blind, Parallel Group, Placebo-controlled Multi-centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients With Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy |
| **Kurztitel** | OlympiA |
| **Studienart** | multizentrisch, Therapiestudie, randomisiert, doppelblind, zweiarmig, kontrolliert |
| **Studienphase** | Phase III |
| **Erkrankung** | Geschlechtsorgane: Brustkrebs: adjuvant |
| **Einschlusskriterien** | - Histologically confirmed non-metastatic primary triple negative invasive adenocarcinoma of the breast. •Invasive Triple Negative Breast Cancer<br>- Documented mutation in BRCA1 or BRCA2 that is predicted to be deleterious or suspected deleterious (known or predicted to be detrimental/lead to loss of function).<br>- Completed adequate breast and axilla surgery.<br>- Completed at least 6 cycles neoadjuvant or adjuvant chemotherapy containing anthracyclines, taxanes or the combination of both. Prior platinum as potentially curative<br>- ECOG 0-1. |
| **Ausschlusskriterien** | - Any previous treatment with a PARP inhibitor, including olaparib and/or known hypersensitivity to any of the excipients of study treatment.<br>- Patients with second primary cancer, EXCEPTIONS: adequately treated non-melanoma skin cancer, curatively treated in situ cancer of the cervix, Ductal Carcinoma in situ (DCIS) of the breast, stage 1 grade 1 endometrial carcinoma, or other solid tumours including lymphomas (without bone marrow involvement) curatively treated with no evidence of disease for 5 years prior to randomization. More than one course of chemotherapy for previous malignancies.<br>- Resting ECG with QTc > 470 msec detected on 2 or more time points within a 24 hour period or family history of long QT syndrome. If ECG demonstrates QTc >470 msec, patient will be eligible only if repeat ECG demonstrates QTc 470 msec.<br>- Concomitant use of known potent CYP3A4 inhibitors such as ketoconazole, itraconazole, ritonavir, indinavir, saquinavir, telithromycin, clarithromycin and nelfinavir.<br>- Whole blood transfusions in the last 120 days prior to entry to the study which may interfere with gBRCA testing |
| **Alter** | 18 Jahre und älter |
| **Molekularer Marker** | BRCA<br>Triple neg (HER2/ER/PR neg)<br>HER2/neu neg./ER pos.<br>HER2/neu neg./PR pos. |
| **Fallzahl** | 1320 |
| **Prüfzentren** | **Sana Klinikum Offenbach** (Rekrutierung beendet)<br>Ambulantes Onkologisches Zentrum<br>Starkenburgring 66<br>63069 Offenbach<br>n.a. Melanie Moschitz<br>Tel: 069 8405 5815<br>Fax: 069 8405 4486<br>Melanie.Moschitz@sana.de |

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| **Sponsor** | Astra Zeneca |
| **Registrierung in anderen Studienregistern** | EudraCT 2013-003839-30<br>ClinicalTrials.gov NCT02032823 |